Affirmed by Supreme Court on March 21, 2000.

PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

BROWN & WILLIAMSON TOBACCO CORPORATION; LORILLARD TOBACCO COMPANY; PHILIP MORRIS, INCORPORATED; RJ REYNOLDS TOBACCO COMPANY,
Plaintiffs-Appellants,

and

COYNE BEAHM, INCORPORATED; LIGGETT GROUP, INCORPORATED,
Plaintiffs,

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of

No. 97-1604

Food and Drugs,
Defendants-Appellees.

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA;

STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WEST VIRGINIA; STATE OF WISCONSIN; THE CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator,
Amici Curiae.

COYNE BEAHM, INCORPORATED; BROWN & WILLIAMSON TOBACCO CORPORATION; PHILIP MORRIS, INCORPORATED; RJ REYNOLDS TOBACCO COMPANY; NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED; UNITED STATES TOBACCO COMPANY; CONWOOD COMPANY, LP; NATIONAL TOBACCO COMPANY, LP; PINKERTON TOBACCO COMPANY; SWISHER INTERNATIONAL, INCORPORATED; CENTRAL CAROLINA GROCERS, INCORPORATED; J.T. DAVENPORT, INCORPORATED; NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED; THE AMERICAN ADVERTISING FEDERATION; AMERICAN ASSOCIATION OF ADVERTISING AGENCIES;

No. 97-1581

ASSOCIATION OF NATIONAL ADVERTISERS, INCORPORATED; MAGAZINE PUBLISHERS OF AMERICA; THE OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, INCORPORATED; POINT OF PURCHASE ADVERTISING INSTITUTE; LORILLARD TOBACCO COMPANY,
Plaintiffs-Appellees,

and

LIGGETT GROUP, INCORPORATED,
Plaintiff,

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of Food and Drugs,
Defendants-Appellants.

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WEST VIRGINIA; STATE OF WISCONSIN; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE;

THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator,
Amici Curiae.

COYNE BEAHM, INCORPORATED; BROWN & WILLIAMSON TOBACCO CORPORATION; LORILLARD TOBACCO COMPANY; PHILIP MORRIS, INCORPORATED; RJ REYNOLDS TOBACCO COMPANY; UNITED STATES TOBACCO COMPANY; CONWOOD COMPANY, LP; NATIONAL TOBACCO COMPANY, LP; PINKERTON TOBACCO COMPANY; SWISHER INTERNATIONAL,

No. 97-1606

INCORPORATED; CENTRAL CAROLINA GROCERS, INCORPORATED; J.T. DAVENPORT, INCORPORATED; NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED; THE AMERICAN ADVERTISING FEDERATION; AMERICAN ASSOCIATION OF ADVERTISING AGENCIES; ASSOCIATION OF NATIONAL ADVERTISERS, INCORPORATED; MAGAZINE

PUBLISHERS OF AMERICA; THE OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, INCORPORATED; POINT OF PURCHASE ADVERTISING INSTITUTE; NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED,
Plaintiffs-Appellees,

and

LIGGETT GROUP, INCORPORATED,
Plaintiff,

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of Food and Drugs,
Defendants-Appellants.

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON;

STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WEST VIRGINIA; STATE OF WISCONSIN; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator,
Amici Curiae.

NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED,
Plaintiffs-Appellants,

v.

DAVID A. KESSLER, Commissioner of the Food & Drug Administration; FOOD & DRUG ADMINISTRATION,
Defendants-Appellees,

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF

No. 97-1614

IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN; STATE OF WEST VIRGINIA; CITY AND COUNTY OF SAN FRANCISCO;

PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN CANCER SOCIETY; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION, ("WLF"); MARIO ANDRETTI, DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator,
Amici Curiae.

Appeals from the United States District Court
for the Middle District of North Carolina, at Greensboro.
William L. Osteen, Sr., District Judge.
(CA-95-591-2, CA-95-593-2, CA-95-665-6, CA-95-706-2)

UNITED STATES TOBACCO COMPANY; BROWN & WILLIAMSON TOBACCO CORPORATION; CONWOOD COMPANY, LP; NATIONAL TOBACCO COMPANY, LP; PINKERTON TOBACCO COMPANY; SWISHER INTERNATIONAL, INCORPORATED; CENTRAL CAROLINA GROCERS, INCORPORATED; J.T. DAVENPORT, INCORPORATED; NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED,
Plaintiffs-Appellants,

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of Food and Drugs,
Defendants-Appellees,

No. 97-1605

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON;

STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN; STATE OF WEST VIRGINIA; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives; LAUCH FAIRCLOTH, United States Senator,
Amici Curiae.

Appeal from the United States District Court
for the Middle District of North Carolina, at Winston-Salem.
William L. Osteen, Sr., District Judge.
(CA-95-665-6)

Argued: June 9, 1998

Decided: August 14, 1998

Before WIDENER, Circuit Judge, HALL, Senior Circuit Judge, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Reversed by published opinion. Judge Widener wrote the opinion, in which Senior Judge Michael joined. Senior Judge Hall wrote a dissenting opinion.

COUNSEL

ARGUED: Gerald Cooper Kell, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Government. Richard Melvyn Cooper, WILLIAMS & CONNOLLY, Washington, D.C.; Larry Bruce Sitton, SMITH, HELMS, MULLISS & MOORE, L.L.P., Greensboro, North Carolina; John L. Oberdorfer, PATTON BOGGS, L.L.P., Washington, D.C.; William C. McLeod, COLLIER, SHANNON, RILL & SCOTT, Washington, D.C., for Private Parties. **ON BRIEF:** Frank W. Hunger, Assistant Attorney General, Walter C. Holton, Jr., United States Attorney, Stephen W. Preston, Deputy Assistant Attorney General, George J. Phillips, Counselor to the Assistant Attorney General, Eugene M. Thirolf, Douglas N. Letter, Scott R. McIntosh, Christine N. Kohl, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Margaret Jane Porter, Chief Counsel, Karen E. Schifter, Patricia J. Kaeding, Associate Chief Counsel, FOOD & DRUG ADMINISTRATION, Rockville, Maryland, for Government. Robert R. Marcus, SMITH, HELMS, MULLISS & MOORE, L.L.P., Greensboro, North Carolina; Norwood Robinson, ROBINSON & LAWING, L.L.P., Winston-Salem, North Carolina; John R. Jordan, Jr., JORDAN, PRICE, WALL, GRAY & JONES, Raleigh, North Carolina; John F. Fithian, G. Kendrick Macdowell, PATTON BOGGS, L.L.P., Washington, D.C.; Eric Rowe, PATTON BOGGS, L.L.P., Greensboro, North Car-

olina; R. Timothy Columbus, Brian A. Dahl, COLLIER, SHANNON, RILL & SCOTT, Washington, D.C.; Ray V. Hartwell, III, Douglas W. Davis, HUNTON & WILLIAMS, Richmond, Virginia, for Private Parties. Hubert H. Humphrey, III, Attorney General, Alan I. Gilbert, Solicitor General, James S. Alexander, Assistant Attorney General, Cheryl Heilman, Assistant Attorney General, STATE OF MINNESOTA, St. Paul, Minnesota, for Amici Curiae State of Minnesota, et al. Allison M. Zieve, David C. Vladeck, Alan B. Morrison, PUBLIC CITIZEN LITIGATION GROUP, Washington, D.C., for Amici Curiae Public Citizen, et al. Dennis B. Fleming, Jr., General Counsel, Michael T. Alexander, Jack Conway, OFFICE OF THE GOVERNOR, Frankfort, Kentucky, for Amicus Curiae Commonwealth of Kentucky. Daniel J. Popeo, David M. Young, WASHINGTON LEGAL FOUNDATION, Washington, D.C., for Amici Curiae Foundation, et al.

OPINION

WIDENER, Circuit Judge:

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pt. 801, et al.). In general, this rule set out regulations restricting the sale and distribution of cigarettes and smokeless tobacco (collectively referred to as tobacco products) to minors and limiting the advertising and promotion of tobacco products. Plaintiffs (cigarette and smokeless tobacco manufacturers, convenience store retailers, and advertisers) filed these consolidated actions in federal district court, challenging the FDA's jurisdiction over tobacco products and seeking declaratory and injunctive relief.**1** Plaintiffs then filed a

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1 When the complaint was filed on August 10, 1995, the FDA had only issued a Notice of Proposed Rulemaking. 60 Fed. Reg. 41,314 (1995). Following a comment period, the FDA adopted the proposed rule in modified form. 61 Fed. Reg. 44,396 (1996). Unless noted otherwise, all references in this opinion are to the final version of the rule published in the Federal Register on August 28, 1996. Where italics appear here within a quotation, they have been added for emphasis unless otherwise indicated.

motion for summary judgment in the district court, alleging that, as a matter of law: (1) Congress has withheld from the FDA the jurisdiction to regulate tobacco products as marketed by plaintiffs; and (2) the Federal Food, Drug, and Cosmetic Act (Act) does not permit the FDA to regulate tobacco products either as drugs or as devices. In denying plaintiffs' motion for summary judgment in part and granting the motion in part, the district court held that Congress did not "[intend] to withhold from FDA" the jurisdiction to regulate tobacco products. Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1388 (M.D.N.C. 1997). The district court also concluded that the FDA had authority to regulate tobacco products under the device provision of the Act, but disapproved the FDA's restrictions on advertising as inconsistent with its statutory authority. Coyne Beahm, 966 F. Supp. at 1393-1400. Finally, the district court stayed implementation of the majority of the FDA's regulations pending appeal.**2** Coyne Beahm, 966 F. Supp. at 1400-01. The district court certified its order for immediate interlocutory appeal pursuant to 28 U.S.C. § 1292(b), Coyne Beahm, 966 F. Supp. at 1401, and by order dated May 13, 1997, this court granted the § 1292(b) petitions for immediate appeal filed by two of the plaintiff groups and the FDA. In addition, the FDA had filed its Notice of Appeal dated May 2, 1997 from the partial injunction granted by the district court. Jurisdiction over the consolidated appeals is proper in this court under 28 U.S.C. §§ 1292(a)(1) and 1292(b).

Because this case arises from a motion for summary judgment, we review the judgment of the district court de novo. Myers v. Finkle, 950 F.2d 165, 167 (4th Cir. 1991). For purposes of these appeals, plaintiffs do not dispute the factual findings of the FDA. Based on our review of the record and the relevant legal authorities, we are of opinion that the FDA lacks jurisdiction to regulate tobacco products. For the reasons set forth below, all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid. Accordingly, we reverse the judgment of the district court.

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2 The district court left in place the FDA's proof of age requirement for tobacco sales and the restrictions on sales to persons under age 18, which had already gone into effect. Coyne Beahm, 966 F. Supp. at 1400. However, all 50 States have already banned the sale of tobacco to minors under state law. See 61 Fed. Reg. at 44,419 (citing a joint letter from 25 state attorneys general and other comments submitted to the FDA).

I. FDA's Asserted Basis for Jurisdiction

The FDA**3** has authority to regulate products only if they fall within one of the categories defined by Congress in the Act.**4** In the jurisdictional determination attached to its August 28, 1996 regulations, the FDA asserted jurisdiction over tobacco products under the drug**5** and device**6** definitions in the Act. 61 Fed. Reg. at 44,628. According to the FDA, tobacco products fit within these definitions because they are "intended to affect the structure or any function of the body." More specifically, the FDA concluded that tobacco products are "combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body."**7** 61

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3 On most occasions, the Act refers to the authority of the Secretary of the Department Health and Human Services (HHS) to take certain actions. However, the Secretary acts through the Commissioner of Food and Drugs. 21 U.S.C. § 393(d)(2). For simplicity, we will refer to any legislative delegation as if made directly to the FDA.

4 The categories of products subject to regulation by the FDA are food, drugs, devices, and cosmetics. 21 U.S.C. § 321.

5 The Act defines "drug" in pertinent part as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C).

6 In relevant part, "device" is defined as an article which is:

> intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

21 U.S.C. § 321(h)(3).

7 A combination product is described as a product that contains a combination of a drug, device, or biological product. 21 U.S.C. § 353(g). Neither party contends that tobacco products contain any "biological product," as that term is used in the Act. See 42 U.S.C. § 262(I) (defining a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings").

Fed. Reg. at 44,628, 44,649-650. Based on its classification of tobacco products as combination products, the FDA claimed that it could exercise its discretion in deciding whether the drug provisions or device provisions of the Act should apply. 61 Fed. Reg. at 44,400. Although finding that tobacco products function primarily as drugs, 61 Fed. Reg. at 45,209-218, the FDA concluded that tobacco products are most properly regulated under the device provisions of the Act, in particular the restricted devices section, 21 U.S.C. § 360j(e).**8** 61 Fed. Reg. at 44,400. The FDA's jurisdictional determination encompasses over 600 pages in the Federal Register; however, its basic premise can be fairly summarized in one sentence. That is, the FDA asserted jurisdiction over tobacco products based on its conclusion that tobacco products fit within the literal definitions of drug and device as set forth in the Act. In short, the FDA's inquiry began and ended with the definitions section of the Act.

We are of opinion that the FDA's limited, mechanistic inquiry is insufficient to determine Congress' intent. Therefore, as directed by Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), we employ the traditional tools of statutory construction to ascertain congressional intent regarding whether the FDA has authority to regulate tobacco products.

II. Jurisdictional Analysis

We begin with the basic proposition that agency power is "not the

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8 Section 360j(e) provides in relevant part:

> (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use --
>
> . . .
>
> (B) upon such other conditions as the Secretary may prescribe in such regulation,
>
> if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

21 U.S.C. § 360j(e).

power to make law. Rather, it is `the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.'" Ernst & Ernst v. Hochfelder, 425 U.S. 185, 213-14 (1976) (quoting Manhattan Gen. Equip. Co. v. Commission, 297 U.S. 129, 134 (1936)). Thus, our initial inquiry is whether Congress intended to delegate to the FDA authority to regulate tobacco products as "customarily marketed."**9** The district court framed the issue as "whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed." Coyne Beahm, 966 F. Supp. at 1380. However, we are of opinion that the issue is correctly framed as whether Congress intended to delegate such jurisdiction to the FDA. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) (stating that "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress"); INS v. Chadha, 462 U.S. 919, 953 n.16, 955 n.19 (1983) (providing that agency action "is always subject to check by the terms of the legislation that authorized it; and if that authority is exceeded it is open to judicial review" and "Congress ultimately controls administrative agencies in the legislation that creates them"). This fundamental misconception by the district court of the principal issue in the case unavoidably skewed the remainder of its analysis.

Applying the principles set forth by the Supreme Court in Chevron, we examine whether Congress intended to give the FDA jurisdiction over tobacco products. Under Chevron, we first consider the intent of Congress because "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, 467 U.S. at 842-43. It is only if the intent of Congress is ambiguous that we defer to a permissible interpretation by the agency. Chevron, 467 U.S. at 843. And we note, with emphasis, that the Supreme Court has stated that "[a] precondition to deference under Chevron is a congressional delegation of administrative authority." Adams Fruit Co. v.

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9 Plaintiffs use the term "customarily marketed" in their briefs to indicate tobacco products marketed with customary claims such as smoking pleasure as opposed to tobacco products marketed with specific therapeutic claims such as weight loss. Unless indicated otherwise, all references in this opinion are to tobacco products as customarily marketed.

Barrett, 494 U.S. 638, 649 (1990). Accordingly, no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority. If the court can ascertain Congress' intent on a particular question by applying the traditional rules of statutory construction, then it must give effect to that intent. Chevron, 467 U.S. at 843 n.9; see also Cabell Huntington Hosp., Inc. v. Shalala, 101 F.3d 984, 986 (4th Cir. 1996) (stating that "[t]he goal of statutory interpretation is to implement congressional intent"). We also note that ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction. See, e.g., Adams Fruit Co., 494 U.S. at 650 (quoting Federal Maritime Comm'n v. Seatrain Lines, Inc., 411 U.S. 726, 745 (1973)) (warning that "an agency may not bootstrap itself into an area in which it has no jurisdiction"); ACLU v. FCC, 823 F.2d 1554, 1567 n. 32 (D.C. Cir. 1987) (stating that"[w]hen an agency's assertion of power into new arenas is under attack, therefore, courts should perform a close and searching analysis of congressional intent, remaining skeptical of the proposition that Congress did not speak to such a fundamental issue"), cert. denied, 485 U.S. 959 (1988); Hi-Craft Clothing Co. v. NLRB, 660 F.2d 910, 916 (3d Cir. 1981) (noting that "[t]he more intense scrutiny that is appropriate when the agency interprets its own authority may be grounded in the unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission").

Although the task of statutory construction generally begins with the actual language of the provision in question, Mead Corp. v. Tilley, 490 U.S. 714, 722 (1989), the inquiry does not end there.**10** The Supreme Court has often emphasized the crucial role of context as a tool of statutory construction. For example, the Court has stated that when construing a statute, courts "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole

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10 In fact, if application of the plain language of a statute "would produce a result demonstrably at odds with the intent of Congress . . . the intent of Congress rather than the strict language controls." Maryland State Dep't of Educ. v. U.S. Dep't of Veterans Affairs, 98 F.3d 165, 169 (4th Cir. 1996) (citing United States v. Ron Pair Enter., Inc., 489 U.S. 235, 242 (1989)), cert. denied, 118 S. Ct. 43 (1997).

law, and to its object and policy." United States Nat'l Bank of Or. v. Independent Ins. Agents of America, Inc., 508 U.S. 439, 455 (1993) (quoting United States v. Heirs of Boisdore, 49 U.S. (8 How.) 113, 122, (1849)); see also Regions Hosp. v. Shalala , 66 U.S.L.W. 4125, 4129 n.5 (U.S. Feb. 24, 1998) (No. 96-1375); Massachusetts v. Morash, 490 U.S. 107, 115 (1989). Thus, the traditional rules of statutory construction to be used in ascertaining congressional intent include: the overall statutory scheme, Offshore Logistics, Inc. v. Tallentire, 477 U.S. 207, 220-221 (1986) (directing courts to examine the language of the statute as a whole); legislative history, Atherton v. FDIC, 65 U.S.L.W. 4062, 4067 (U.S. Jan. 14, 1997) (No. 95-928); "the history of evolving congressional regulation in the area," Dunn v. CFTC, 65 U.S.L.W. 4141, 4144 (U.S. Feb. 25, 1997) (No. 95-1181); and a consideration of other relevant statutes, United States v. Stewart, 311 U.S. 60, 64 (1940) (explaining that"all acts in pari materia are to be taken together as if they were one law") (italics in original). With these general principles in mind, we begin our inquiry into the issue of whether Congress intended to delegate jurisdiction over tobacco products to the FDA.

A. Intrinsic Evidence

The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory text. In fact, the Court instructs that the inquiry ends with the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." Robinson v. Shell Oil, 65 U.S.L.W. 4103, 4104 (U.S. Feb. 18, 1997) (No. 95-1376) (quoting Ron Pair Enter., 489 U.S. at 240).

However, the flaw in the limited approach suggested by the FDA and taken by the district court is that they examine only the literal meaning of the statutory definitions of drug and device.**11** See FDA

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11 For example, in its jurisdictional analysis, the district court purported to examine the "Text of the Federal Food, Drug, and Cosmetic Act." Coyne Beahm, 966 F. Supp. at 1380. However, the court mentioned only the definitions sections of the statute and ignored the text of all of the mandatory operative provisions of the Act.

Red Br. at 34 (stating that "the jurisdictional inquiry is at an end with the conclusion that cigarettes and smokeless tobacco are `intended to affect the structure of any function of the body' within the meaning of the Act's drug and device provisions"); see also Coyne Beahm, 966 F. Supp. at 1380.

A mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices. However, an initial problem with the government's theory is that the definitions of drug and device require not only that the article "affect the structure or any function of the body," but also that these effects be intended. 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). As noted by the district court, "no court has ever found that a product is `intended for use' or `intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use." Coyne Beahm, 966 F. Supp. at 1390. Even the FDA does not contend that tobacco manufacturers make any such claims. Coyne Beahm, 966 F. Supp. at 1389 n.14.

Even if we were to accept the FDA's position that no other inquiry is permissible if tobacco products fall within the literal definition of drug or device, the jurisdictional inquiry would not end there. Both the FDA and the district court failed to examine the literal definitions in view of the language and structure of the Act as a whole. Such holistic approach to statutory construction is well-supported by the case law. See, e.g., Robinson, 65 U.S.L.W. at 4104 (stating that statutory language must be examined by "reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole"); Gustafson v. Alloyd Co., 513 U.S. 561, 570 (1995) (instructing that acts of Congress"should not be read as a series of unrelated and isolated provisions"); United States Nat'l Bank, 508 U.S. at 455 (quoting United Savings Ass'n of Texas v. Timbers of Inwood Forest Assoc., Ltd., 484 U.S. 365, 371 (1988)) (explaining that statutory interpretation is a "holistic endeavor" that must include, at a minimum, an examination of the statute's full text, its structure, and the subject matter). Accordingly, our task is to examine whether tobacco products fit into the overall regulatory scheme created by Congress.

According to FDA Deputy Commissioner Schultz, "[a] fundamental precept of drug and device regulation in this country is that these

products must be proven safe and effective before they can be sold." Statement by FDA Deputy Commissioner William B. Schultz before the Senate Comm. on Labor and Human Resources, 104th Cong., p. 8 (Feb. 22, 1996). In fact, the FDA's congressionally-established mission statement provides that the FDA is charged with protecting the public health by ensuring that human drugs are "safe and effective" and that "there is a reasonable assurance of the safety and effectiveness of devices intended for human use." 21 U.S.C. § 393(b)(2)(B), (C). During its rulemaking, the FDA found that tobacco products are "dangerous," "unsafe," and the cause of"great pain and suffering from illness such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. at 44,412. In addition, the FDA determined that over 400,000 people die each year from tobacco use. 61 Fed. Reg. at 44,412. Yet, the FDA has proposed to regulate tobacco products under a statutory provision that requires conditions on sale and distribution which provide a reasonable assurance of safety. 21 U.S.C. § 360j(e). According to the FDA, a determination of safety under the Act requires consideration of the risks of a product compared to the "countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." 61 Fed. Reg. at 44,412-13. Thus, the FDA concluded that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweigh the risks of leaving tobacco products on the market. 61 Fed. Reg. at 44,405, 44,412-44,413.

But that test is contrary to the statute. The statutory provision, 21 U.S.C. § 360c(a)(2)(C), provides that safety and effectiveness are to be determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." See also United States v. Rutherford, 442 U.S. 544, 556 (1979) (stating that "a drug is unsafe if its potential for inflicting death and physical injury is not offset by the possibility of therapeutic benefit"). According to the language of § 360c(a)(2)(C), the FDA's obligation is to strike a balance between the risks and benefits of the use of a certain product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market. The FDA is unable to state any real health benefit derived from leaving tobacco products on the market. This is not to say that there are not other public policy reasons, such as impact on the national economy and the potential for a black market, weighing against a ban on

tobacco products. However, this type of decision involving countervailing national policy concerns is just the type of decision left for Congress. By statute, the FDA's authority is limited to the balancing of health benefits and risks. 21 U.S.C. § 360c(a)(2)(C). Thus, its attempted analogy between tobacco products and chemotherapy drugs is not well taken. 61 Fed. Reg. at 44,413. These cancer-fighting drugs may be considered high-risk, but they have not been deemed "unsafe" by the FDA. Under the Act, the key to allowing these drugs to remain on the market is that their use produces affirmative health benefits which outweigh their risks. 21 U.S.C. § 360c(a)(2)(C). According to the FDA's own findings, tobacco products do not meet this test, for there is no health benefit from the use of tobacco. The FDA's inquiry into whether the risks of removing tobacco products from the market are greater than the risks of leaving them on the market is irrelevant under § 360c(a)(2)(C).

In the proposed regulations, the FDA characterized tobacco products as combination products containing drug and device components, but purported to regulate tobacco products as restricted devices under § 360j(e) of the Act. Section 360j(e) permits the FDA to place restrictions on the sale, distribution or use of a product which are necessary for a "reasonable assurance of safety" of the product. 21 U.S.C. § 360j(e). However, based on the FDA's characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety. Thus, the FDA cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation. In addition to the fundamental conflicts described above, at least six internal inconsistencies arise when tobacco products are forced into the drug or device regulatory schemes of the Act.

First, § 355(a) of the Act requires that all new drugs be approved by the FDA before marketing. 21 U.S.C. § 355(a). The Act requires the FDA to disapprove applications for new drugs **12** if the drug is

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12 In relevant part, the Act defines a "new drug" as:

> Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . .

21 U.S.C. § 321(p)(1).

deemed unsafe or if there is not substantial evidence of its effectiveness. 21 U.S.C. § 355(d). This mandatory approval process presents an insurmountable problem for the FDA with respect to tobacco products because of the FDA's finding that they are unsafe. 61 Fed. Reg. at 44,412. In fact, the FDA has conceded that under the mandatory approval provisions, tobacco products would constitute unapproved new drugs. 60 Fed. Reg. 41,348 (1995) (FDA Proposed Rulemaking). As such, the Act would require the prohibition of the distribution and marketing of tobacco products. 21 U.S.C. §§ 331(d), 355(a).

The FDA attempts to avoid the problem inherent in the new drug approval requirement by classifying tobacco products as combination products and then choosing to regulate them as devices rather than as drugs. The Act directs the FDA to determine the primary mode of action of a combination product. 21 U.S.C. § 353(g)(1). If the FDA determines that the primary mode of action is that of a drug, then it must assign "primary jurisdiction" over the product to the persons charged with premarket review of drugs. 21 U.S.C.§ 353(g)(1)(A), (B). The FDA concedes that the "primary mode of action" of tobacco products is that of a drug.**13** FDA Red Br. at 26 (citing 61 Fed. Reg. at 45,209-18; 44,400-03). Yet, it chose to regulate tobacco products devices under § 360j(e) of the Act. This transparent action by the FDA, obvious sophistry, taken in order to avoid the new drug provisions of the Act, reinforces the conclusion that regulation of tobacco products under the Act was not intended by Congress. However, the FDA's classification of tobacco products as devices could not avoid similar problems caused by other provisions of the Act.

Section 331(a) of the Act prohibits the introduction into or delivery in interstate commerce of any drug or device that is misbranded. 21 U.S.C. § 331(a). Under § 352(j), a drug or device is deemed to be misbranded if it is dangerous to health when used in the manner suggested in the labeling. 21 U.S.C. § 352(j). The FDA has concluded that the use of tobacco products is dangerous to health. 61 Fed. Reg.

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13 Interestingly, the FDA chose to regulate tobacco products as devices even though it has regulated the nicotine products within its jurisdiction - nicotine patches, nicotine gum, and nicotine nasal sprays - as drugs. Approved Drug Products with Therapeutic Equivalence Evaluations, 1762 Food Drug Cosm. L. Rep. (CCH) 3-220, 221 (FDA May 29, 1996).

at 44,412. Thus, it is impossible for the labeling of tobacco products to suggest a nondangerous use. Accordingly, #8E8E # 331(a) and 352(j) operate to make the continued marketing of tobacco products illegal.

A drug or device is also considered misbranded, and thus prohibited under § 331(a), if it does not include"adequate directions for use." 21 U.S.C. § 352(f)(1). According to the FDA, the requirement of adequate directions for use means "directions under which the layman can use a device safely and for the purposes for which it is intended." 61 Fed. Reg. at 44,464. The FDA can exempt drugs and devices from § 352(f)(1)'s directions requirement, but only if the information is "not necessary for the protection of public health." 21 U.S.C. § 352(f). The FDA has previously interpreted § 352(f) to mean that an exemption from the direction requirements may be granted when other circumstances (such as a physician's prescription) can reasonably assure safe use of the drug or device. 21 C.F.R. §§ 201.100-201.129, 801.109-801.127 (1996).

The FDA now contends that an exemption for tobacco products is appropriate, 61 Fed. Reg. at 44,410, because everyone knows how to use tobacco products and thus directions are not needed. See 61 Fed. Reg. at 44,465 (stating that tobacco products are"one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge."). However, the FDA violated its own interpretation of the Act by exempting tobacco products under § 352(f) without any assurances of safety. Because of the FDA's finding that tobacco products are unsafe, 61 Fed. Reg. at 44,412, it is impossible to provide directions for safe use as required by the statute. In addition, the exemption is inapplicable because no assurance of safety can be given for inherently unsafe products such as tobacco. Again, the FDA's need to apply the statutory exemption demonstrates that the Act does not and cannot apply to tobacco products.

Similarly, a drug or device is also considered misbranded, and thus prohibited by § 331(a), if it fails to bear"adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Unlike § 352(f)(1), this section does not permit any exemptions from the warning requirement. In support of its proposed regulations, the FDA cited widespread use of tobacco products

by minors and focused on controlling youth use as a means of decreasing tobacco-related illnesses and deaths. See 61 Fed. Reg. at 45,238-243 (characterizing youth use of tobacco products as a "pediatric disease"). The FDA concluded that the warnings mandated by other federal statutes satisfy the Act's requirement for adequate warnings to children even though none of the statutorily-prescribed warnings address the particular dangers of youth use repeatedly emphasized by the FDA. See 15 U.S.C. § 1333, 4402 (requiring Surgeon General warnings about health risks posed by tobacco products); see also 61 Fed. Reg. at 44,465. The FDA was constrained to find that the warnings mandated by other federal statutes are sufficient because the applicable federal statutes do not permit federal agencies to add to or modify the congressionally-mandated warnings. 15 U.S.C. §§ 1334(a), 4406(a). Again, the contortions that the FDA has gone through demonstrate that Congress did not intend its jurisdictional grant to the FDA to extend to tobacco products.

Furthermore, under 21 U.S.C. § 360c(b)(1), all devices intended for human use must be classified into one of three categories, Class I, II, or III, based on ascending degrees of dangerousness. Placement is appropriate in the class that will provide a "reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)-(C). As discussed above, safety and effectiveness are determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). Three years after it first introduced the proposed regulations, the FDA has yet to place tobacco products into one of the three categories. However, the agency's own findings with respect to dangers to health require classification of tobacco products as a Class III device subject to premarket approval because they "[present] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II); see also 61 Fed. Reg. at 44,398, 44,412 (discussing dangers of tobacco use). Under the premarket approval process, tobacco products could not be approved without a showing that there is a reasonable assurance of safety and effectiveness of the products when used in the manner suggested by the labeling. 21 U.S.C. § 360c(a)(1)(C). The FDA contends that it will classify tobacco products at some point in the future and that the long delay is consistent with both the statutory framework and the agency's prior actions for other devices. 61 Fed. Reg. at 44,412; FDA Red Br. at 45.

However, the real problem with attempting a classification is that all three categories of devices require reasonable assurances of safety and effectiveness for the product. 21 U.S.C. § 360c(a)(1). As discussed earlier, the FDA cannot provide reasonable assurances of safety for a product that it has found to be inherently unsafe and dangerous. Thus, it has not, and more importantly, cannot comply with Congress' statutory classification directive because complying with the statute would trigger a ban on tobacco products, a result not intended by Congress.

Finally, the Act requires the FDA to issue an immediate cease-distribution order for all products found to cause"serious, adverse health consequences or death." 21 U.S.C. § 360h(e)(1).**14** This order begins an agency process that may ultimately result in a recall order for the device. 21 U.S.C. § 360h(e)(2). The FDA has found that "tobacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths." 61 Fed. Reg. at 44,398 (citations omitted). According to the terms of the Act, these findings, standing alone, mandate that the FDA issue a cease-distribution order for tobacco products. Nevertheless, the FDA has no intention of complying with the requirements of the Act. See 61 Fed. Reg. at 44,419 (stating that the FDA will not ban tobacco products). The necessity of the FDA's avoidance of the statutory directives again demonstrates that Congress did not intend that the Act regulate tobacco products. A faithful application of the statutory language would lead to a ban on tobacco products - a result not intended by Congress.

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14 In relevant part, § 360h(e)(1) provides:

> If the [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the [FDA] shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device) -
>
> (A) to immediately cease distribution of such device;
>
> . . .

21 U.S.C. § 360h(e)(1).

The FDA makes a linguistic argument in an attempt to avoid the problem presented by this section. The statute provides that if the FDA finds there is a reasonable probability that a device will cause health problems or death, then the FDA "shall issue an order requiring . . . [the immediate] cease distribution of such device." 21 U.S.C. § 360h(e)(1)(A). However, the FDA contends that "shall" should be interpreted to mean "may." FDA Red Br. at 42-43. Even if we were to adopt this interpretation, the substance of our analysis would not change. As discussed above, the FDA has made the requisite finding of dangerousness under the statute. Thus, even if"shall" were interpreted as "may," the FDA still could exercise its discretion under the statute and ban tobacco products. And a failure to ban a product as dangerous as is tobacco, by the FDA's own findings, would necessarily be an abuse of discretion. But because an absolute ban falls outside the scope of congressional intent, construing the Act to cover tobacco products would be inconsistent with the will of Congress.

As demonstrated by the examples provided above, the FDA's need to maneuver around the obstacles created by the operative provisions of the Act reflects congressional intent not to include tobacco products within the scope of the FDA's authority. The FDA argues that even if it has misapplied the Act, this error does not bear on the jurisdictional issue. However, the point is not merely that the FDA misapplied the Act, but these examples demonstrate the FDA's need to ignore and misapply the operative provisions of the Act before it can attain its end, not the end contemplated by Congress. Cf. United States v. Two Plastic Drums, 984 F.2d 814, 819 (7th Cir. 1993) (rejecting another recent attempt by the FDA to enlarge its jurisdiction and stating that "the only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme"). The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco products.

We do not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public. However, the Supreme Court has warned that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop."

62 Cases of Jam v. United States, 340 U.S. 593, 600 (1951). Based on our examination of the regulatory scheme created by Congress, we are of opinion that the FDA is attempting to stretch the Act beyond the scope intended by Congress.

B. Extrinsic Evidence

Pursuant to Chevron's instruction to employ the traditional tools of statutory construction, we now examine the events surrounding the 1938 passage of the Act as well as subsequent statements and actions by Congress and the FDA. These individual events are like pieces of a puzzle in that no single event is outcome determinative. However, when viewed as a whole, it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products in 1938 when it passed the Act. See MCI Telecomm. Corp. v. AT&T , 512 U.S. 218, 228 (1994) (stating that relevant time for determining congressional intent on meaning of statute is when controlling statute enacted). As discussed above, the fact that the operative provisions of the Act simply cannot accommodate tobacco products is a clear indication of congressional intent. Cf. Gustafson, 513 U.S. at 569 (explaining that an operative provision of the Securities Act of 1933 does not define prospectus, the term at issue, but "does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme"). Subsequent events outside the language of the statute only confirm our understanding of Congress' intent.

1. Historical Actions of the FDA

From 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction. And, as early as 1898, the Supreme Court of Tennessee acknowledged the dangerous nature of tobacco products, characterizing cigarettes as "wholly noxious and deleterious to health," "inherently bad, and bad only," and "widely condemned as pernicious altogether." Austin v. State, 48 S.W. 305, 306 (Tenn. 1898). Yet, the statute preceding the Act, the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), did not mention tobacco. As early as 1914, the FDA's predecessor agency stated that it had authority to regulate tobacco products if their labeling indicated use for "the cure, mitigation, or prevention of a disease," but not if labeled or used for

"smoking or chewing or as snuff and not for medicinal purposes." Bureau of Chemistry, U.S. Dept. of Agriculture, 13 Service and Regulatory Announcements 24 (Apr. 2, 1914). Enacted in 1938, the present Act expanded the definition of drug from the definition provided in the Pure Food and Drugs Act of 1906 and also granted the FDA new authority to regulate "devices." Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938). However, neither the Act nor its legislative history mention tobacco products.**15**

In the 60 years following the passage of the Act, the FDA has repeatedly informed Congress that cigarettes marketed without therapeutic claims do not fit within the scope of the Act. Ever since its beginning in the 1930s, the FDA has taken the position and made statements indicating that the Act did not apply to cigarettes marketed without specific health claims. FDA/Dep't of Justice Brief in ASH v. Harris (No. 79-1397), at 16. Again, in 1963, an FDA Bureau of Enforcement Guideline stated that "[t]he statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic." Letter to Directors of Bureaus and Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), reprinted in Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454, 92d Cong. 240 (1972). When Congress later examined the issue of the FDA's jurisdiction during its consideration of tobacco-specific legislation, FDA Commissioner Charles Edwards testified regarding the FDA's lack of authority over cigarettes and stated that"if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended [use]."**16** Hearings on S. 1454 at 239. The Commissioner

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15 Two of the main supporters of the Act were representatives from the two leading tobacco States - Senator Bailey (D-NC) and Representative Chapman (D-KY). See 83 Cong. Rec. 9094 (1938). In fact, Sen. Bailey and Rep. Chapman were among Senate and House managers of the Act in the Conference Committee. Had there been any indication that the Act might apply to tobacco products, we can only assume that such members of Congress would have expressed opposition to the Act.

16 The Commissioner cited several cases in support of the FDA's conclusion that it lacked authority over cigarettes as customarily marketed.

took the position that the Federal Cigarette Labeling and Advertising Act, discussed in greater detail below, reinforced that "the regulation of cigarettes is to be the domain of Congress." Hearings on S. 1454 at 242. The Commissioner then concluded that "labeling or banning cigarettes is a step that can be take[n] only by Congress. Any such move by the FDA would be inconsistent with the clear congressional intent." Hearings on S. 1454 at 242.

In 1977, Action on Smoking and Health (ASH), a public health group, petitioned the FDA to regulate cigarettes. ASH claimed that cigarettes were drugs because they contain nicotine which produces addiction in many smokers, and particularly in youth. Citizen Petition, FDA Docket No. 77P-0185, at 4-11 (May 26, 1977)[G. Br. Att. 77]. In rejecting ASH's petition,**17** the FDA cited a 1953 Second Circuit opinion, FTC v. Liggett & Myers Tobacco Co., 203 F.2d 955 (2d Cir. 1953), affirming on opinion below, 108 F. Supp. 573 (S.D.N.Y. 1952), for the proposition that cigarettes marketed without health claims by the vendor are not within the FDA's jurisdiction. Specifically, the FDA quoted with approval the following language from the court's opinion:

> The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be

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See, e.g., FTC v. Liggett & Myers Tobacco Co. , 203 F.2d 955 (2d Cir. 1953), affirming on opinion below, 108 F. Supp. 573 (S.D.N.Y. 1952); United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959); United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1952).

17 A federal appeals court upheld the FDA's denial of jurisdiction. See ASH v. Harris, 655 F.2d 236 (D.C. Cir. 1980). In upholding the FDA's denial of jurisdiction, the court emphasized the relevance of the remarks of the district court in Liggett. In construing the identical language of the definitions in the Federal Trade Commission Act, the Liggett court stated: "[s]urely, the legislators did not mean to be as all-inclusive as a literal interpretation of [the definitions] would compel us to be." ASH, 655 F.2d at 240 (quoting Liggett & Myers, 108 F. Supp. at 576).

> included as an article "intended to affect the functions of the body of man" or in any other definition of "drug."

See Letter from FDA Commissioner Donald Kennedy to John F. Banzhaf, III, at 3 (Dec. 5, 1977) (quoting Liggett & Myers, 108 F. Supp. at 577) (stating that the FDA's consistent position has been that cigarettes marketed without health claims by vendors are not drugs within the Act).

In 1978, ASH filed a second petition, claiming that cigarettes were devices under the Act and thus were within the scope of the FDA's jurisdiction. Citizen Petition, FDA Docket No. 78P-0338 (Oct. 2, 1978). After reviewing the legislative history of the Act, the FDA stated that "[i]nsofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under [the definition of device]. Therefore, no rulemaking is permissible as a matter of law." Letter from FDA Commissioner Jere E. Goyan to John F. Banzhaf, III and Peter N. Georgiades, at 12 (Nov. 25, 1980). In considering the effect of the Medical Device Amendments of 1976 which modified the definition of device to its current formulation, the FDA Commissioner stated:

> Specifically, there is no evidence in the legislative history that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were"devices" within the prior definition.
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> The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

Goyan/Banzhaf Letter, at 3. The FDA's holdings and statements that the Act fails to provide "authority suitable to the regulation of cigarettes" are consistent with part II.A's conclusion, supra, that the Act's regulatory scheme simply cannot accommodate tobacco products.

Again in 1989, the FDA Commissioner stated that:"it doesn't look like it is possible to regulate [tobacco products] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Hearings Before the Subcomm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations, 100th Cong., 2d Sess. 409 (1989). The above statements evidence the FDA's position from 1914 until the present rulemaking attempt that, as a matter of law, it did not have jurisdiction to regulate tobacco products as customarily marketed. The FDA's public, consistent, and longstanding interpretation**18** of the Act gains even more significance when viewed in conjunction with the actions of Congress during the same time period.

2. Congressional Inaction

We recognize the general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation. See Brecht v. Abrahamson, 507 U.S. 619, 632 (1993) (noting that "[a]s a general matter, `we are reluctant to draw inferences from Congress's failure to act'") (quoting Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 306 (1988)). However, under certain circumstances, inaction by Congress may be interpreted as legislative ratification of or acquiescence to an agency's position. See Bob Jones Univ. v. United States, 461 U.S. 574, 601 (1983) (stating that "[i]n view of its prolonged and acute awareness of so important an issue, Congress' failure to act on the bills proposed on this subject provides added support for conclud-

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18 We do not mean to suggest that an agency is always irrevocably bound by its prior interpretations of a statute. However, we note that an agency's interpretation of a statutory provision that conflicts with the agency's earlier interpretation is "`entitled to considerably less deference' than a consistently held agency view." Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) (quoting Watt v. Alaska, 451 U.S. 259, 273 (1981)). In addition, the evidence of legislative ratification also weighs against the FDA's actions in the present case.

ing that Congress acquiesced in the IRS rulings"). In Bob Jones, the Court examined Congress' failure to modify two IRS rulings when the public and Congress were well aware of the position of the IRS. Bob Jones, 461 U.S. 599-602. In finding legislative acquiescence to the IRS position, the Court emphasized: extensive hearings held by Congress on the issue; the introduction and failure of numerous bills in Congress introduced to overturn the IRS's interpretation of the Internal Revenue Code; and Congress' awareness of the IRS position when enacting other, related legislation. Bob Jones, 461 U.S. at 599-601; see also United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 137 (1985) (finding legislative acquiescence and explaining that "a refusal by Congress to overrule an agency's construction of legislation" is particularly relevant "where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it").

We are of opinion that the matter before us presents an equally strong case of legislative acquiescence.**19** As noted by the district court, Congress has introduced numerous bills that would have granted the FDA jurisdiction over tobacco products. See Coyne Beahm, 966 F. Supp. at 1382 (stating that "members of Congress agreed with FDA's assertions that it lacked jurisdiction" and thus introduced bills expressly granting the FDA jurisdiction "in an effort to remedy the situation"). In fact, the district court listed 15 different bills introduced in Congress which would have expressly granted the FDA jurisdiction over tobacco products. Coyne Beahm, 966 F. Supp. at 1382. However, none of these bills were enacted. As discussed above, FDA officials have testified at many congressional hearings regarding the FDA's lack of jurisdiction over tobacco products. See also Coyne Beahm, 966 F. Supp. at 1381. Thus, Congress has been well aware of the FDA's position that it lacked jurisdiction over tobacco products since 1914. On several occasions, Congress has enacted legislation to deal specifically with the dangers of tobacco products, but has never enacted legislation to overturn the FDA's

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19 The district court attempted to distinguish the Bob Jones and Riverside Bayview cases by noting that they involved agency action rather than statements by an agency that it did not have jurisdiction to act. Coyne Beahm, 966 F. Supp. at 1383. We fail to see any real distinction and thus find the cases applicable.

interpretation of its jurisdiction under the Act. Accordingly, this is not a case where congressional inaction demonstrates"unawareness, preoccupation, or paralysis." See Zuber v. Allen , 396 U.S. 168, 185-86 n.21 (1969). We believe that the actions rejected and taken by Congress with respect to the regulation of tobacco provide strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products.

3. Congress' Tobacco-Specific Legislation

Under Chevron's instruction to apply the traditional rules of statutory construction, it is also appropriate to consider the provisions of the "whole law, and . . . its object and policy" in ascertaining the will of Congress. Dole v. United Steelworkers of America, 494 U.S. 26, 35 (1990) (quoting Pilot Life Ins. Co. v. Dedeaux , 481 U.S. 41, 51 (1987)). Having examined the Act and prior actions of the FDA and Congress, we now take a closer look at three statutes and related amendments (collectively referred to as the tobacco-specific legislation) enacted by Congress for the purpose of addressing public health concerns about the use of tobacco products.

The issue is not, in the words of the stalking horse set up by the government, whether these three statutes partially repeal or amend the Act to withhold jurisdiction over tobacco products from the FDA. FDA Red Br. at 57. Rather, we examine the tobacco-specific legislation as a part of our inquiry into congressional intent. As discussed above, we are of opinion that the statutory text, viewed as a coherent whole, clearly indicates that Congress did not intend the FDA's original jurisdictional grant to include tobacco products. Thus, the subsequent enactment of tobacco-specific legislation provides corroborating evidence of established congressional intent.

In January 1964, the publication of the first Surgeon General's report on smoking and health called the federal government's attention to the dangers of tobacco products. Dept. of Health, Education and Welfare, Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service (1964); see also H.R. Rep. No. 289, 91st Cong., 1st Sess., at 5 (characterizing the 1964 Surgeon General's Report as the "principal basis" for regulatory efforts). Shortly thereafter, the House Committee on Interstate and

Foreign Commerce initiated a series of hearings regarding the federal government's role in dealing with smoking-related health problems. Committee Chairman, Representative Oren Harris, stated that:

> The purpose of these hearings will be, if we can reach that point, to determine the extent of authority under existing law to deal with the various aspects of this general field, and to determine whether any action of the Congress is warranted in the interest of public health. In other words, we want to find out under our responsibility whether or not legislative action is necessary, and if so, what kind.

Hearings Before the Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, 88th Cong., 2d Sess. 23 (1964).

During the course of these hearings, Congress considered and rejected the option of granting the FDA jurisdiction over tobacco products. Of the eleven bills submitted to the Committee, two would have expressly amended the Act to make it applicable to tobacco products. 1964 Hearings at 2-12. These two bills proposed expansion of the Act to cover tobacco products by creating a new category of products subject to FDA jurisdiction. See 1964 Hearings at 4-7 (suggesting creation of new category entitled "smoking products"). These two bills also proposed new operative provisions applicable only to "smoking products."**20** 1964 Hearings at 4-7. As part of the hearings, Surgeon General Terry was asked whether the Department of Health, Education, and Welfare (HEW), the FDA's parent department, had authority to regulate tobacco products. Dr. Terry's unqualified response was that his department did not believe that it had "such authority in existing laws governing the Public Health Service and Food and Drug Administration." 1964 Hearings at 56. Similar testimony was later provided by the Deputy Commissioner of the FDA. See Cigarette Labeling and Advertising: Hearings Before the House

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20 The fact that the two proposed bills created a new jurisdictional category and new operative provisions for tobacco products is consistent with our analysis in part II.A, supra, which concludes that the current structure of the Act cannot accommodate tobacco products.

Comm. on Interstate and Foreign Commerce, 89th Cong., 2d Sess. 193 (1965) (statement of Deputy Commissioner Rankin that "[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); see also 111 Cong. Rec. 13431 (1965). In addition, the Secretary of HEW, Anthony J. Celebrezze, warned the Committee that giving the FDA jurisdiction over tobacco products "might well" lead to a ban and that such a ban would be contrary to the intent of Congress and the will of the American public. See 1964 Hearings at 18 (stating that a ban would be "contrary to what, we understand, is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people").

Following the hearings and consideration of the various bills, Congress responded to the Surgeon General's report by enacting The Federal Cigarette Labeling and Advertising Act (Cigarette Labeling Act), Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331 et seq.). In general, the Cigarette Labeling Act required manufacturers to place specific health-hazard warnings from the Surgeon General on cigarette packaging, advertising, and billboards. 15 U.S.C. § 1333. The Cigarette Labeling Act also set forth congressional policy regarding regulation of tobacco products:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby -
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331. Thus, the express goal of the Cigarette Labeling Act is to warn consumers about the health hazards of smoking while also protecting the national economy.

The district court apparently considered that the plaintiffs claimed that the separate preemption provision of the Cigarette Labeling Act precluded any further regulation of tobacco products except by Congress. See Coyne Beahm, 966 F. Supp. at 1385-1386. We do not think that the claim was so broad then, certainly it is not so broad now. While it is true that 15 U.S.C. § 1334, requires that no statement relating to smoking or health other than the statement required by § 1333, shall be required on any cigarette package, that is not a statement excluding other regulation of tobacco products. But the fact that Congress has, some 27 years after the establishment of the FDA in its present form, enacted the Cigarette Labeling Act, is strong evidence that Congress has reserved for itself the regulation of tobacco products rather than delegating that regulation to the FDA.

Congressional policy, as set out in the Cigarette Labeling Act, cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products. First, by enacting the Cigarette Labeling Act rather than other proposed legislation, Congress clearly rejected the proposed regulatory role for the FDA. Next, the Act charges the FDA with protecting the public health, but does not authorize the FDA to consider protection of commerce and the national economy. Thus, by the terms of its enabling statute, the FDA is not capable of complying with Congress' stated policy regarding the regulation of tobacco products. In addition, the congressionally-established regulatory plan of the Cigarette Labeling Act directly contradicts the FDA's mandatory requirements set forth in the Act. As discussed supra in part II.A, the Act prohibits the sale or distribution of unsafe devices. See, e.g., 21 U.S.C. §§ 331(a), 352(j). In contrast, the Cigarette Labeling Act recognizes the unsafe and dangerous nature of cigarettes, but permits continued marketing with consumer warnings. 15 U.S.C. §§ 1331, 1333. The decision by Congress to allow continued marketing of unsafe products cannot be reconciled with the operative provisions of the Act, primarily because the Act does not allow FDA consideration of the factors involved in Congress' policy determination. See 15 U.S.C. § 1331(2) (establishing policy of protecting "commerce and the national economy").

Finally, in developing the Cigarette Labeling Act, Congress clearly considered and rejected a role for the FDA. The government does not produce any legislative history to the contrary. The legislative history of the Cigarette Labeling Act is thus important to understanding congressional intent because it reflects the historical context in which the Cigarette Labeling Act was developed. See Radowich v. United States Att'y, 658 F.2d 957, 961 (4th Cir. 1981) (stating that courts should look at the "clearly expressed intention as expressed without dissent in the legislative history" to be certain that their construction of a statute is consistent with the "manifest purpose as clearly mirrored in the legislative history"). Thus, the Cigarette Labeling Act and the context in which it was enacted provides evidence of Congress' intent that the FDA not have jurisdiction over tobacco products. Subsequent legislation by Congress reinforces our understanding of this expressed congressional intent.

The Cigarette Labeling Act's advertising and labeling regulations originally were set to expire on June 30, 1969. In response, the Federal Communications Commission (FCC) introduced a proposal to ban all television and radio cigarette advertising. 34 Fed. Reg. 1959 (1969). In addition, the Federal Trade Commission (FTC) renewed its proposed rule from 1964. See 34 Fed. Reg. 7917 (1969) (citing health hazards of smoking and proposing warning statements for cigarette packages and advertisements).**21** Again, Congress debated the role of administrative agencies in the regulation of tobacco products. See generally Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong., 1st Sess. (1969). The House Report stated:

> The regulations [proposed by the FCC and the FTC] raise basic constitutional questions and would affect the growing, sale, and manufacturing of tobacco for cigarettes and the persons involved in or affected by those activities. These activities cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.

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21 We note that the FDA took no action at this time.

. . .

> Aside from the questions of constitutional and statutory law which the two agencies' proposed rules raise, they are an assumption by these agencies of policymaking with respect to a subject matter on which the Congress has made policy . . ., [and] has stated its intention to be the exclusive policymaker on the subject matter . . . .

H.R. Rep. No. 289, at 4-5.

Following these debates and hearings, Congress amended the Cigarette Labeling Act by enacting the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970). Basically, the 1969 Act reenacted the Cigarette Labeling Act, but with several amendments.**22** Notably, Congress did not amend or replace 15 U.S.C. § 1331, the provision setting out its policy determination regarding the regulation of tobacco products.

Congress showed a continuing interest in the regulation of tobacco products with the Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. §§ 290aa et seq.). These amendments require the Secretary of HHS, FDA's parent agency, to submit certain reports to Congress every three years. 42 U.S.C. § 290aa-2(b). The statute directs the Secretary to report to Congress current findings on "the addictive property of tobacco" and to recommend "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C.§ 290aa-2(b)(2)-(3). This statute evidences Congress' awareness of the addictive nature of tobacco products and its intent to retain control over further regulatory action.

In 1984, Congress again amended the Cigarette Labeling Act, but retained the basic regulatory approach established in 1965. See Com-

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22 For example, the 1970 amendments changed the wording of the warning to be included on cigarette packages, 15 U.S.C. § 1333; revised § 1334's express preemption provision; and made it unlawful to advertise cigarettes on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 1335.

prehensive Smoking Education Act (Smoking Education Act), Pub. L. No. 98-474, 98 Stat. 2200 (1984) (amending the Cigarette Labeling Act). The Smoking Education Act required rotating warnings on cigarette packaging and advertising, 15 U.S.C. § 1333; established an Interagency Committee on Smoking and Health, including members from the FTC, the Department of Education, and the Department of Labor, but not from the FDA, 15 U.S.C. § 1341(b); and required annual disclosure of tobacco ingredients to the Secretary of HHS, 15 U.S.C. § 1335a. Quoting U.S. Surgeon General Dr. C. Everett Koop, the House Report recommending this legislation described cigarette smoking as "the most important public issue of our time." H.R. Rep. No. 805, 98th Cong., 2d Sess., at 12 (1984). Consistent with the prior actions of Congress discussed above, the House Report recognized that "[f]ederal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes." H.R. Rep. 805, at 12.

In 1986, Congress created a similar regulatory program for smokeless tobacco, but with some additions.**23** Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act), Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C.§§ 4401-4408). In general, the Smokeless Tobacco Act required specific health warnings in smokeless tobacco advertising and on packaging, 15 U.S.C. § 4402(a),(b); authorized the FTC to issue specified regulations regarding the content and form of label warnings, 15 U.S.C. § 4402(c); banned advertising on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 4402(f); and required annual ingredient and nicotine-level reporting to the HHS Secretary, 15 U.S.C. § 4403. In addition, the Smokeless Tobacco Act authorized the Secretary of HHS to develop a program for informing the public of the health hazards caused by use of smokeless tobacco. 15 U.S.C. § 4401(a). Specifically, the Secretary is instructed to make this information available to school systems for educational purposes. 15 U.S.C. § 4401(a)(1)(B). The statute also provided for technical and financial assistance to States for their development of educational programs about the dangers of smokeless tobacco and for establishing

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23 It is worth noting that Congress adopted a very similar approach to the one taken in the Cigarette Labeling Act, even though it had expressly recognized the addictive nature of tobacco. 42 U.S.C. § 290aa-2(b)(2).

18 as the minimum age for purchasing smokeless tobacco. 15 U.S.C. § 4401(b).**24** Finally, the Smokeless Tobacco Act requires the Secretary of HHS to submit biennial reports to Congress containing "a description of the effects of health education efforts," "an evaluation of the health effects of smokeless tobacco products," and "recommendations for legislation and administrative action." 15 U.S.C. § 4407(a).

Like the Cigarette Labeling Act, the Smokeless Tobacco Act also contains an express preemption provision. See 15 U.S.C. § 4406 (providing that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement"). However, as discussed in relation to the Cigarette Labeling Act, this express preemption provision does not detract from our examination of the statute as a tool for determining congressional intent. In recommending passage of the Smokeless Tobacco Act, the House Report cited particular concerns about the popularity of smokeless tobacco with minors. See S. Rep. No. 209, 99th Cong., at 4 (1985), reprinted in 1986 U.S.C.C.A.N. 7, 10 (stating that "a major reason for the development of a legislative proposal is the alarming incidence of use by children"). Thus, in 1986, Congress considered the very issues that the FDA now purports to address in its proposed regulations.

Within the context of the FDA's repeated stated positions that it had no jurisdiction, Congress enacted comprehensive legislation addressing many of the activities that the FDA now attempts to regulate, based on the same concerns relating to youth use now cited by the FDA. The enactment of the Smokeless Tobacco Act in no way supports a conclusion that Congress intended to give the FDA jurisdiction over tobacco products. To the contrary, the detailed scheme created by Congress evidences its intent to retain authority over regulation of smokeless tobacco. Cf. Patterson v. McLean Credit Union,

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24 As discussed below, Congress built on the youth education and age limit provisions of the Smokeless Tobacco Act in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub. L. No. 102-321, 106 Stat. 394 (codified at 42 U.S.C. § 300x-26).

491 U.S. 164, 181 (1989) (stating that courts "should be reluctant . . . to read an earlier statute broadly where the result is to circumvent the detailed remedial scheme constructed in a later statute"). The FDA may not, without empowerment by Congress, construct what it believes is a "better" regulatory scheme. MCI, 512 U.S. at 234. If the FDA believed that additional regulation was needed, the Secretary should have recommended such action to Congress, as directed in the Smokeless Tobacco Act. 15 U.S.C. § 4407(a)(4).

In 1992, Congress again addressed the problem of youth access to tobacco products. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub. L. No. 102-321, 106 Stat. 394, focused on regulation at the state level by providing financial incentives to States which enact and enforce access restrictions for individuals under age 18. 42 U.S.C. § 300x-26.**25**

The 1992 Amendments express clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products. However, the FDA's proposed regulatory scheme would preempt much state regulation in this area, including more stringent regulations than those proposed by the FDA. The Act prohibits States from imposing on devices any requirements "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a). Thus, if the Act applied to tobacco products, § 360k(a) would prohibit States from addressing the problem of youth access. The FDA responds, FDA Red Br. p. 67, n. 16, that States "might" qualify for exemptions from preemption under § 360k(b). However, the possibility of a discretionary exemption does not take away the inherent conflict between the state regula-

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25 More specifically, States are eligible for the financial incentives only if they: (1) prohibit sales to individuals under age 18, 42 U.S.C. § 300x-26(a)(1); (2) enforce the prohibition in a way that"can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18," 42 U.S.C. § 300x-26(b)(1); (3) conduct "random, unannounced inspections" of retailers to check compliance, 42 U.S.C. § 300x-26(b)(2)(A); and (4) make annual reports to the HHS Secretary regarding the manner and success of state enforcement activities, 42 U.S.C. § 300x-26(b)(2)(B).

tory role established by Congress and the FDA's proposed scheme. In developing its regulatory scheme for tobacco products, Congress made a policy determination that state participation was necessary for effective regulation of youth access. Allowing the FDA to override this decision would be contrary to congressional intent.

Over the last 60 years, Congress has enacted numerous statutes and amendments for the regulation of tobacco products. Throughout this period, Congress was well aware of the dangers of tobacco products and of the FDA's consistent position that it had no jurisdiction over tobacco products. Yet, Congress took no steps to overturn the FDA's interpretation of the Act, that it had no jurisdiction over tobacco products as customarily used. In fact, Congress deliberately rejected a role for the FDA during its consideration of various legislation from 1965 through 1993.**26** Instead, Congress developed a regulatory scheme whereby it retained the position of policymaker for the industry.**27** In addition, it developed a scheme whereby designated agencies would periodically report any new information and recommendations for legislation or regulation to Congress.**28** Taken together, these actions by Congress are relevant and corroborative evidence that Congress never intended to give the FDA jurisdiction over tobacco products.

III. Conclusion

This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to

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26 Between 1965 and 1993, at least 13 bills were introduced in Congress which would have given the FDA jurisdiction over tobacco products. None of these bills were enacted.

27 Although Congress has given the FTC limited authority to regulate advertising related to tobacco products, this power is limited by the tobacco-specific legislation. 15 U.S.C. §§ 1336m, 4404-06.

28 The HHS, FTC, and Interagency Committee are all directed to make periodic reports to Congress including information on the health effects of tobacco products, the addictive nature of tobacco products, cigarette advertising. See e.g., 15 U.S.C. §§ 1337(a), (b), 1341(a)-(c); 42 U.S.C. § 290aa-2.

make this type of major policy decision. As the Supreme Court has previously stated about a different agency and its enabling statute, neither federal agencies nor the courts can substitute their policy judgments for those of Congress. See MCI, 512 U.S. at 234 (stating that "our estimations, and the [FCC's] estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934"). In rejecting the agency's interpretation of its enabling statute, the MCI Court characterized the agency's action as "effectively the introduction of a whole new regime of regulation . .. which may well be a better regime but is not the one that Congress established." MCI, 512 U.S. at 234. Accordingly, we do not, indeed cannot, pass judgment on the merits of the regulatory scheme proposed by the FDA. By its ultra vires action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand.

We are thus of opinion that Congress did not intend to delegate jurisdiction over tobacco products to the FDA. Accordingly, the judgment of the district court is

REVERSED.**29**

HALL, Circuit Judge, dissenting:

The FDCA delegates to the FDA the duty of promulgating and enforcing regulations aimed at protecting the nation's citizens from misbranded and unsafe drugs and food. After years of considering an array of evidence, much of it only recently brought to light, the FDA

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29 This footnote is added to make clear that the judgment of the district court regarding the construction of 21 U.S.C. § 360j(e), Coyne Beahm, 966 F. Supp. at 1399-1400, is vacated. The district court's construction of § 360j(e) was based on its erroneous holding that the FDA had authority to promulgate regulations regarding tobacco products. Had the district court reached the correct conclusion on the jurisdictional issue, there would have been no occasion to address the construction of § 360j(e). Accordingly, we vacate the district court's decision on that issue which is the subject of the government's appeal. We express no opinion on that question, and our decision should not be construed as either agreeing with or disagreeing with the district court's decision on the construction of § 360j(e).

decided to regulate a product that is estimated to cause some 400,000 deaths a year. While not actually disputing that tobacco products deliver a drug, nicotine, into the body, the majority would deny to the FDA the authority to act to address this acknowledged health threat. I dissent.

Tobacco products fit comfortably into the FDCA's definitions of "drug" and "device." Inasmuch as cigarettes and smokeless tobacco are responsible for illness and death on a vast scale, FDA regulations aimed at curbing tobacco use by children cannot possibly be contrary to the general intent of the FDCA to protect the public health. But even when we expand our search for legislative intent beyond the words of the statute, the evidence falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA. Therefore, on the major question before us, I would affirm the district court's denial of summary judgment to the companies to the extent such judgment turns on the issue of the FDA's authority to regulate tobacco products.

As a consequence of this view, I must also reach those subordinate issues not discussed by the majority. I would affirm the denial of summary judgment to the companies on the issue of the FDA's choice of the "combination-products" regulatory scheme. I believe, however, that the district court erred in ruling that the FDA cannot, as a matter of statutory law, restrict the advertising of tobacco pursuant to the agency's authority to regulate the "sale" of such products.

I

When reviewing an agency's construction of a statute, we must first ask "whether Congress has directly spoken to the precise question at issue." Chevron, U.S.A., Inc., v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984). The usual rule is to enforce the plain language of a statute according to its terms. United States v. Ron Pair Enters., Inc., 489 U.S. 235, 241 (1989). Whether the language is plain is "determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole." Robinson v. Shell Oil Company, 519 U.S. 337, ___ , 117 S. Ct. 843, 846 (1997). Here, the language is

plain, and the context does not command a result contrary to the plain meaning.

The majority devotes approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim: "[T]he term `drug' means . . . articles (other than food) intended to affect the structure or function of the body." 21 U.S.C.§ 321(g)(1)(C). While as much as conceding that tobacco products fit the FDCA's "literal" definition of drug, the majority concentrates instead on what it believes is abundant evidence elsewhere demonstrating that Congress has never intended that tobacco come under FDA authority. Despite the apparent agreement about the "literal" meaning of "drug" and "device," a few words are necessary to set the stage before moving on to a discussion of the "context" of the FDCA.

A

The rulemaking record contains voluminous evidence of the pharmacological effects of nicotine; in addition to being highly addictive, nicotine acts as a stimulant, tranquilizer and appetite suppressant. See 61 Fed. Reg. 44665-66 (1996). Under these assumed facts, nicotine clearly "affect[s] the structure or function of the body of man . . .", and I do not understand the majority to be saying otherwise. The only arguable impediment to a complete fit between the terms of the statute and tobacco products is the word "intended."

B

Building on the conclusion that the nicotine in tobacco products is highly addictive, the FDA proffered four independent rationales to satisfy the additional requirement that tobacco products be "intended" to affect the body: (1) a reasonable manufacturer would foresee that consumers would use the product to satisfy addiction, see 61 Fed. Reg. 44634, 44701-39; (2) most consumers do in fact use tobacco products to satisfy addiction, see id. at 44233; (3) the manufacturers have long known that consumers use the products for the pharmacological effects, see id. at 44849; and (4) the manufacturers design the products to deliver active doses of nicotine, see id. at 44951. On reasoning with which I agree, the district court held that the FDA could proffer evidence in support of the first and second of these rationales.

Coyne Beahm, 966 F. Supp. at 1388-92. In addition, I would also permit the use of recently disclosed evidence, including heretofore-secret company documents, that establish that the companies have known about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine.

My dictionary contains the following definitions of"intend": "1. To have in mind: PLAN. 2a. To design for a particular purpose. b. To have in mind for a particular purpose." WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY (1984). As a matter of simple English, the resultant effect on the body -- nicotine addiction-- is intended when the manufacturer (as we are assuming for the purposes of this appeal) deliberately designs the product to have that effect. This meaning is the primary, literal, and most common one attached to the word "intend," and it is ordinarily the one we should use. See Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 187 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). The majority's argument does not convince me that we should abandon this common sense rule in this situation.

Prior to these rules, the FDA had "asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers." Action on Smoking and Health v. Harris, 655 F.2d 236, 239 & n.7 (D.C. Cir. 1980) [hereinafter ASH] (citing as examples United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959), in which cigarettes were marketed as weight reduction aids, and United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953), in which cigarettes were marketed as helping to prevent respiratory diseases). No other court, however, has been confronted with the type and quantity of evidence collected during the rulemaking process in this case; the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before.

Products deliberately designed to create and sustain addiction are not likely to be marketed as such; indeed, such products are more likely listed elsewhere in Title 21 among the illegal controlled substances. It strikes me as patently absurd to contend that cigarettes and

smokeless tobacco, products that are (under the assumed facts) actually designed to exert powerful and quintessentially drug-like effects on the users, should escape FDA regulation because the products are marketed as essential accoutrements of a more exciting or more sophisticated lifestyle.

II

Tobacco products, then, come squarely within the plain terms of the FDCA. If the words of a statute are plain, "absent any `indication that doing so would frustrate Congress's clear intention or yield patent absurdity, our obligation is to apply the statute as Congress wrote it.'" Hubbard v. United States, 514 U.S. 695, 703 (1995) (quoting BFP v. Resolution Trust Corporation, 511 U.S. 531, 570 (1994) (Souter, J., dissenting)), quoted in Dunn v. Commodity Futures Trading Commission, 117 S. Ct. 913, 916 (1997). The questions, then, should be: Does upholding FDA jurisdiction over tobacco frustrate clear congressional intent to withhold such jurisdiction? Is it patently absurd? Does it "conflict with any other section of the Code, or with any important state or federal interest, [or] is a contrary view suggested by the legislative history[?]" Ron Pair, 489 U.S. at 243. In other words, given the plain language used in § 321(g)(1)(C), the question should be whether the intent manifested by the words used -- that tobacco products are "drugs delivery devices" subject to FDA regulation -- is trumped by evidence to the contrary.

The majority seeks to show that the "context" of these readily understood words demonstrates that Congress really meant something else where tobacco is concerned. This search for context takes us into "the overall regulatory scheme created by Congress" (Maj. op. at 20) and "the history of evolving congressional regulation in the area" (Maj. op. at 19) (citation omitted), the legislative history of the FDCA and related statutes, and even congressional inaction. I will address each avenue explored by the majority.

A

The majority opens with this argument: The FDA's mandate is to prevent the marketing of any drug or device that is found to be unsafe; tobacco products are unsafe; to allow the continued sale of

cigarettes is completely at odds with such mandate; ergo, the regulations must be struck down. But whether the regulations contravene the statute is a question wholly apart from whether any regulations could be issued. How the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all, particularly when it is agreed that the power to regulate under the FDCA includes the power (under the assumed facts) to ban tobacco products completely. The FDA made an eminently reasonable decision to focus on preventing addiction among children while permitting sales to adults. See Fed. Reg. 44398-99, 44412-13. It is no argument to say that the FDA can do nothing because it could have done more.

B

The majority's analysis of the "extrinsic evidence" of congressional intent stands on three legs: The lack of any mention of tobacco in the statute itself or the legislative history of the 1938 Act; the FDA's consistent disavowal of any intention of taking jurisdiction over tobacco, and, concomitantly, the general assumption that the agency was right; and the series of tobacco-related statutes enacted over the last thirty years.**1**

The FDCA

In construing remedial legislation, we must be ever mindful of the salutary purpose of the statute.

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we

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1 As a corollary to this third point, the majority also relies on congressional refusal to enact legislation that would have expressly given the FDA the authority it now claims. See Maj. op. at 32-34. To whatever extent this inaction may be interpreted as "ratification" of the FDA's prior (no tobacco jurisdiction) position, it would appear that Congress's continued inaction in the face of all that has followed the FDA's announcement of the proposed rule three years ago (see 60 Fed. Reg. 41314) would more than offset any ratification effect to be gleaned from the earlier inaction.

> think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates--and equally clearly, broader than any strict medical definition might otherwise allow. [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health . . . .

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).**2** The majority starts off on the wrong foot when it asks "whether Congress intended to delegate jurisdiction over tobacco products to the FDA." Maj. op. at 19.

Congress did not "intend" that any particular product be included; as the district court noted, "[r]ather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products." Coyne Beahm v. FDA, 966 F. Supp. at 1380. An exhaustive list of covered products was neither feasible nor necessary; effective regulation required flexibility within broad parameters.

Pointing out the obvious -- that the FDCA was not originally directed at tobacco -- gets us nowhere. No one contends that Congress foresaw in 1938 that tobacco was or might someday be included as a "drug" under the FDCA. The operative congressional intent at the outset was simply to confer broad discretionary powers on the FDA to regulate "drugs" and "devices." The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose.

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2 Justice Frankfurter put it this way:

> The purposes of this legislation [FDCA] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

United States v. Dotterweich, 320 U.S. 277, 280 (1943).

FDA's Prior Position

Until the rulemaking began in 1995, the FDA had interpreted the FDCA to include tobacco products only when health claims were made. See Maj. op. at 29-30. The agency's refusal even extended to opposing citizens' petitions to regulate cigarettes on essentially the same basis that is used in the regulations today. See, e.g., ASH, 655 F.2d 236. The agency's current position is a response to the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the additive effect of tobacco products. When the early tobacco-specific statutes were being debated in Congress, the essential link between tobacco and illness had not yet been proven to the satisfaction of all. For instance, during the floor debate on amendments to the FCLAA, Rep. Perkins stated that

> [i]t is my feeling that not one of the tobacco farmers in my district would knowingly produce any commodity which, when consumed, would cause the dread diseases which have been claimed to be associated with tobacco. But the claims . . . are not proved. Tobacco has been impeached in passion but it had not been convicted in fact. Facts, cold hard facts are the basis upon which congress should legislate.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong. 16 (1969). Well, the "cold hard facts" are now in.

It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. See Rust v. Sullivan, 500 U.S. 173, 186-87 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court added the following caveat:

> Nothing in this opinion should suggest that the[FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An admin-

> istrative agency is clearly free to revise its interpretations.... The very structure of the [FDCA] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action. . . . [citations omitted].

ASH, 655 F.2d at 242 n.10.

Under the facts found by the FDA during the rulemaking process, it is now a scientific certainty that nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction; even more important to my mind is the new evidence that the manufacturers design their products to sustain such addiction. The administrative record in this case is a perfect illustration of why an agency's opportunity to adopt a new position should remain open.

The Tobacco Statutes

As products of the democratic process, each tobacco-specific statute is a balance of health, economic, and other concerns. The majority cites this body of legislation as "corroborating evidence of established congressional intent" to withhold jurisdiction over tobacco from the FDA. Maj. op. at 34. Again, I think the majority's approach ignores the fundamental source of intent, the words of the statute itself. Nevertheless, closer examination of these tobacco statutes reveals that they form something less than Congress's "comprehensive program" to address the tobacco problem. Absent a discernable intent to exclude future FDA action,**3** that these statutes were written with knowledge that the FDA foreswore jurisdiction over tobacco does not supply that intent.

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3 Congress certainly knows how to exempt tobacco. The only mention of tobacco in the FDCA was added in 1994 to explicitly remove tobacco from the new exemption of "dietary supplements" from the definition of "drug." See Pub. L. No. 103-407,§ 3(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)). The criminal laws regarding narcotics incorporate the definition of "drug" found in the FDCA, see 21 U.S.C. § 802(12), but the definition of "controlled substance," which includes "a drug," specifically excludes tobacco. See 21 U.S.C. § 802(6).

The first in this series, the Federal Cigarette Labeling and Advertising Act (FCLAA),**4** was enacted in response to the Surgeon General's groundbreaking 1964 report linking smoking to health problems. The companies describe it as a statute that "set the boundaries of the federal regulatory role," "clearly expresses a congressional intent that precludes FDA jurisdiction over tobacco products," "embodied the view that Congress, itself, should retain all policy making authority as to tobacco, even in areas open to regulation," "ratified the established understanding that FDA does not have jurisdiction over tobacco products," "ruled out any later reading of the FDCA as an `implicit' delegation to FDA . . . of authority to decide whether or how to regulate tobacco products and whether to ban them." Companies' Opening br. 13, 18-20. An examination of the statute reveals something considerably more modest, something that will not bear anything approaching the weight placed upon it by the companies or the majority.

The majority's focus is § 1331, which reads:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby--
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

This is a far cry from a comprehensive federal tobacco program; it is

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4 The Comprehensive Smokeless Tobacco Health and Education Act, 15 U.S.C. §§ 4401-4407, more or less mirrors the FCLAA.

little more than a mild response to one of the earliest official recognitions of an emerging health issue.

The narrowness of the FCLAA was emphasized in Banzhaf v. FCC, 405 F.2d 1082 (D.C. Cir. 1968), where the court was confronted with a post-FCLAA ruling by the FCC that required radio and television stations that carried cigarette commercials to devote significant broadcast time to permit the case to be made against smoking. Then, as they do today, the tobacco companies argued that the FCLAA embodied a clear congressional intent to preclude intrusions into the regulation of tobacco by any agency. See id. at 1088. Judge Bazelon, however, saw things differently:

> [T]here are positive indications that Congress's "comprehensive program" was directed at the relatively narrow specific issue of regulation of "cigarette labeling and advertising." . . . Nothing in the [FCLAA] indicates that Congress had any intent at all with respect to other types of regulation by other agencies-- much less that it specifically meant to foreclose all such regulation. If it meant to do anything so dramatic, it might reasonably be expected to have said so directly . . . .

Id. at 1089 (footnotes omitted) (quotations in original).**5** The next thirty years would see several more small steps that, even when considered together, fall far short of a comprehensive program, and even shorter of a demonstration that Congress intended to preclude the exercise of jurisdiction now being asserted by the FDA.

Following the FCLAA, the next step in what the companies characterize as Congress's ongoing program was the Public Health Cigarette Smoking Act of 1969, which amended the FCLAA in response to proposed incursions into the field by the FCC and FTC by way of proposed regulations that would have restricted tobacco advertising.

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5 In Cippolone v. Liggett Group, Inc., 505 U.S. 504, 514 (1992), the Court described the purposes of the FCLAA as informing the public of the health risks and "protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling advertising regulations" [footnote omitted].

Again, Congress addressed only advertising, this time in the electronic media, and short-circuited the roles proposed by the agencies for themselves.

Thirteen years later, Congress enacted the Alcohol and Drug Abuse Amendments of 1983, which simply directs the Secretary of HHS to report to Congress every three years on "the health consequences of drug abuse in the United States [and] current research findings made with respect to drug abuse, including current findings on . . . the addictive property of tobacco" and to include recommendations for "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. § 290aa-2(b). This does not, as the majority asserts, "evidence[ ] Congress' . . . intent to retain control over further regulatory action." Maj. op. at 39. It is more an acknowledgment that because the HHS (and the FDA), as the experts in the complex field of drug abuse, had and would continue to have a crucial role to play, the Secretary was required to ask Congress for any additional tools it needed get to perform that role effectively.

The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 [ADAMHA], the last brick in the purported congressional tobacco program, provides financial incentives to the States to enforce their own restrictions on access to tobacco by minors. The majority argues that the FDA regulations would conflict with this congressional determination that the States should take an active role in addressing the youth access problem because the FDCA preempts any different restrictions on devices. See 21 U.S.C. § 360k(a). This overstates the case.

ADAMHA restructured block grant programs aimed at substance abuse and mental health services; only a few provisions relate to underage smoking. See 42 U.S.C. § 300x-26. ADAMHA does not demonstrate an intent on Congress's part that the states "take the primary role" in addressing the problem of underage smoking, and it certainly does not "establish" a regulatory role for the states. Maj. op. at 42-43. Although the FDA's proposed regulations would preempt some state laws, the exercise of FDA authority over tobacco would not "prohibit the States from addressing the problem of youth access." Id. The proposed rule can co-exist with most of the states' separate laws prohibiting sales to minors and imposing other restrictions on

tobacco sales. Even the few more stringent state or local restrictions that are preempted by the FDA's proposed regulations (see 61 Fed. Reg. 44548-50) might qualify for an exemption from preemption, thereby further minimizing conflicts. See 21 U.S.C. § 360k(b). An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other. See Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253 (1992) ("Redundancies across statutes are not unusual events in drafting, and so long as there is no `positive repugnancy' between two laws, a court must give effect to both") (internal citation omitted).

C

Tobacco is different from the articles commonly associated with the word "drugs," the FDA regulations are indeed the result of turn-around in agency thinking, and tobacco was most probably not on anyone's mind when the FDCA was enacted. But the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert -- the FDA -- the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, we are bound to uphold FDA jurisdiction.

The FDA's denials that it had any authority over tobacco were certainly part of the background against which Congress passed tobacco-related legislation in the thirty years following the Surgeon General's 1964 report, but this series of statutes is hardly an argument for "legislative ratification" (Maj. op. at 32 n.18) of the FDA's prior position that the agency was powerless to act. It is agreed, moreover, that an agency is permitted to change its mind, particularly in response to new facts, so the real question is whether all that has gone before -- the tobacco statutes, the consistent denials by the FDA -- is sufficient to demonstrate a clear intent on Congress's part to preclude FDA jurisdiction. The evidence offered by the companies falls far short.

III

Having decided that the FDA has no jurisdiction over tobacco products, the majority had no reason to address whether cigarettes and

smokeless tobacco were "devices" and whether the choice of regulatory regime -- as a combination product, pursuant to the device authorities -- was permissible. I agree with and adopt the district court's reasoning on these points entirely. See Coyne Beahm, 966 F. Supp. at 1393-97.

IV

Another issue not reached by the majority is whether the FDA may restrict the advertising of tobacco products.**6** On this point, I disagree with the district court's conclusion that the advertising regulations exceeded the FDA's statutory authority.

The FDA found that "cigarette and smokeless tobacco use begins almost exclusively in childhood and adolescence." 61 Fed. Reg. 45239. Minors are particularly vulnerable to Madison Avenue's exhortations, plastered on racing cars and outfield fences, to be cool and smoke, be manly and chew, and the FDA found"compelling evidence that promotional campaigns can be extremely effective in attracting young people to tobacco products." Id. at 45247.**7** The FDA chose to attack the problem by attempting to reduce the pressures to start using tobacco in the first place.

The pertinent portion of the of the 1976 Medical Device Amendments, 21 U.S.C. § 360j(e), provides:

> The Secretary may by regulation require that a device be restricted to sale, distribution, or use . . . [by prescription]

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6 In view of its ruling on statutory grounds, it was unnecessary for the district court to reach the companies' constitutional objections to the advertising restrictions. Coyne Beahm, 966 F. Supp. at 1400 n.33. Because neither party has briefed the First Amendment issue, I do not discuss it here.

7 For example, one study cited in the rulemaking record found that "30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking." Id. at 45246 (citing Fischer, Schwartz & Richards, Brand Logo Recognition by Children Aged 3 to 6 Years, Mickey Mouse and Old Joe the Camel, Journal of the American Medical Association, 1991).

> or upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

The FDA relies on this section as authority for the regulations restricting the advertising of tobacco products, its rationale being that the authority to restrict the "sale" of or to impose "other conditions" on a product includes within it the authority to restrict the means by which such sales are generated.

Examples of obviously permissible restrictions of the "sale" of a product are regulations regarding where, when, by whom, and to whom a product can be sold. But is a restriction on advertising a restriction of the "sale" of a product? The district court found that the plain meaning of the words precluded advertising restrictions: "Both as ordinarily defined and as used in the phrase`may . . . be restricted to sale, distribution, or use,' the word `sale' does not encompass the advertising or promotion of a product." Coyne Beahm, 966 F. Supp. at 1398 (footnote omitted). But even the dictionary entry cited in the district court's opinion defines "sale" as"the act of selling"; the term "sales" is defined as "[a]ctivities involved in the selling of goods and services." Id. at n.23. Under a Chevron step-two analysis -- "if the statute is silent or ambiguous with respect to the specific issue, the question is whether the agency's answer is based on a permissible construction of the statute[,]" Chevron , 467 U.S. at 843 (footnote omitted) -- we need only find that the agency construction is a reasonable one, not the best one. See id. at n.11. I believe the term "sale" is ambiguous enough to encompass the concept of"offer for sale."

The district court also distilled an intent to withhold the authority asserted by the FDA from the use of the terms "offer for sale" and "advertising" elsewhere in 1976 legislation. See Coyne Beahm, 966 F. Supp. at 1398-99. However, while the "language and design of the statute as a whole" (K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988)) might raise a question about the extent of the FDA's authority in this area, it does not mandate a conclusion that Congress intended to foreclose the FDA from imposing advertising restrictions. There is simply no conclusive evidence of intent either way; the phrase is sim-

ply ambiguous, both in isolation and with reference to the context in which it is used.

The term "sale, distribution and use," which is used only once in the entire FDCA, can reasonably be construed to include all aspects of a product's journey from the factory to the store and to the home. As I have noted above, tobacco is different from the run-of-the-mine drugs and devices in the FDA's bailiwick, and the nature of the differences dictate new approaches to fight the dangers posed. Because the precise approach chosen might not have been considered by the drafters of the statute does not necessarily preclude it. The interpretation is a reasonable one and, therefore, we must defer to the agency.

V

I would affirm the district court's judgment to the extent that it denies summary judgment to the tobacco companies on the issues of the FDA's authority to regulate tobacco products under the FDCA and to regulate such products as "combination products." I would vacate the judgment below to the extent it grants summary judgment to the companies on the issue of the FDA's authority to regulate the advertising of tobacco products.